

REMARKS

Claims 1, 11, 17, and 18 have been amended. New claims 19-21 have been added. No new matter has been added. Reconsideration is respectfully requested in view of the foregoing amendments and the following remarks.

Applicants' Response to Rejections Under 35 U.S.C. §102 over Kuwahara

Claims 1-6 and 8-17 are rejected under 35 U.S.C. § 102(b), as allegedly being anticipated by WO 99/04727 to Kuwahara et al., which is translated as U.S. Patent No. 6,346,119 (hereinafter "Kuwahara"). Applicants respectfully traverse the rejection on the basis that Kuwahara fails to disclose, teach, or suggest each and every element of Applicants' amended claims.

The Examiner alleges that Kuwahara discloses a stent-graft with a tubular fabric and a deformable stent. According to the Examiner, the graft tube is made of a woven fabric having a plurality of fibers, and the graft tube is capable of being used as a vascular, endovascular or intraluminal prosthesis. The Examiner further contends that Kuwahara discloses polyester fibers made of polyethylene naphthalate (PEN), a coating for the prosthesis, fabric having about 20-100 filaments, and filaments having a denier of 50 and 100.

The Examiner admits, however, that Applicants' claims are not identically disclosed in Kuwahara. According to the Examiner, Applicants' claimed physical properties, i.e., that the material is radiation resistant, hydrolytically stable, and stable at a temperature of at least about 120°C, are not explicitly recited in Kuwahara. The Examiner alleges, however, that Applicants' claimed physical properties are inherent in the disclosure of Kuwahara.

Applicants have amended claims 1, 11, and 17 to further define the invention. In particular, Applicants have added a recitation to further define the polymeric filaments or yarns of the implantable prosthesis fabric. As amended, the fabric contains polymeric yarns that have

been drawn to produce directionally aligned or oriented yarns having increased strength and dimensional stability. Support for this amendment can be found on pages 12-13, and 19 of the specification as originally filed. Accordingly, Applicants' invention provides implantable prostheses that are thinner, more abrasion resistant and overall more durable than conventional prior art implants.

Nowhere in Kuwahara are such drawn polymeric yarns, or the step of drawing such yarns, disclosed, taught, or suggested. Kuwahara merely discloses a graft comprising two tubes disposed on the inner and outer surfaces of a stent. The graft tubes of Kuwahara are made of plain polyester resin fibers. Kuwahara does not disclose drawn polymeric fibers which are directionally oriented, nor any of the resulting properties attained thereby. Therefore, Kuwahara fails to disclose each and every limitation of Applicants' amended claims.

Moreover, to establish inherency, a characteristic must necessarily flow from the teachings of the applied reference. The fact that such a characteristic may be present is not sufficient for inherency. The Examiner, however, has not explained how the graft of Kuwahara necessarily includes the allegedly inherent physical properties of Applicants' claims, i.e., that the material is radiation resistant, hydrolytically stable, and stable at a temperature of at least about 120°C.

Therefore, Kuwahara does not disclose every limitation of Applicants' amended claims. To be an effective anticipatory reference, a cited document must disclose each and every limitation recited in a claim under examination. As such, Kuwahara must fail as an anticipatory reference, and Applicants respectfully request reconsideration and withdrawal of the Section 102 rejection.

Applicants' Response to Rejections Under 35 U.S.C. §103 over Kuwahara and Vanney

Claim 18 is rejected under 35 U.S.C. § 103(a), as allegedly being obvious over Kuwahara in view of U.S. Patent No. 5,876,436 to Vanney et al. (hereinafter "Vanney"). Applicants respectfully traverse the rejection on the basis that the Examiner has failed to establish a prima facie case of obviousness.

The Examiner admits that Kuwahara does not identically disclose each and every element of claim 18. In particular, the Examiner explains that Kuwahara does not explicitly disclose producing the prosthesis under steam sterilization. The Examiner asserts, however, that Vanney teaches steam sterilization of a fabric prosthesis, and thus, claim 18 is obvious. More specifically, the Examiner alleges that it would have been obvious for one of skill in the art to use steam sterilization as taught in Vanney with a stent graft of Kuwahara to provide a safe, sterile implant for the patient.

Applicants have amended claim 18 to include the step of drawing the polymeric filaments prior to forming the implantable prosthesis. Support for this amendment can be found on pages 12-13, and 19 of the specification as originally filed. In addressing Kuwahara as a reference, Applicants have already described in detail that it fails to provide (either expressly or inherently) devices or methods as recited in Applicants' amended claims. Nowhere in Kuwahara is the step of drawing polymeric yarns disclosed, taught, or suggested.


Moreover, Vanney fails to cure the deficiencies of Kuwahara as a reference. Vanney was cited merely for its teaching of steam sterilization of a fabric prosthesis. Vanney relates to rotatable cuffs for heart valve prostheses, and contains no disclosure of relevance to Applicants' amended claim 18. More specifically, nowhere in Vanney is there any disclosure, teaching, or suggestion related to the drawing of polymeric yarns.

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Accordingly, amended claim 18 is not obvious in view of the teachings of Kuwahara in combination with Vanney. Applicants respectfully request reconsideration and withdrawal of the Section 103 rejection based on this combination.

Applicants' undersigned attorney may be reached by telephone at the number given below. All correspondence should continue to be directed to the address given below.

Respectfully submitted,


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VERSION OF AMENDMENT WITH MARKINGS

SHOWING CHANGES MADE

IN THE CLAIMS:

1. (Twice Amended) An implantable prosthesis having improved mechanical and chemical properties comprising:

a radiation resistant and hydrolytically stable biocompatible fabric having inner and outer surfaces and first and second ends;

said fabric having a textile construction of a plurality of polymeric filaments comprising a naphthalene dicarboxylate derivative, wherein said radiation resistant and hydrolytically stable biocompatible fabric is stable at a temperature of at least about 120°C,

and wherein said fabric comprises a plurality of drawn polymeric yarns which are directionally aligned or oriented to increase strength and dimensional stability.

11. (Twice Amended) An implantable prosthesis having improved mechanical and chemical properties comprising:

a radiation resistant and hydrolytically stable biocompatible tubular fabric of a textile construction,

said fabric having a plurality of yarns selected from the group consisting of polyethylene naphthalate, polybutylene naphthalate and combinations thereof, wherein said radiation resistant and hydrolytically stable biocompatible fabric is stable at a temperature of at least about 120°C,

and wherein said fabric comprises a plurality of drawn polymeric yarns which are directionally aligned or oriented to increase strength and dimensional stability.

17. (Twice Amended) Method for making a radiation and thermal resistant and hydrolytically stable, steam sterilizable biocompatible prosthesis comprising:

a) drawing a plurality of polymeric filaments comprising a naphthalene dicarboxylate derivative;

ba) providing a fabric having an inner and outer surface and first and second ends, said fabric having a plurality of said drawn polymeric filaments ~~comprising a naphthalene dicarboxylate derivative~~, wherein said fabric being stable at a temperature of at least about 120°C;

cb) selecting a textile construction pattern; and

de) forming said prosthesis in accordance with a textile construction pattern.

18. (Twice Amended) Implantable prosthesis comprising a fabric having improved chemical and mechanical properties formed by the process comprising:

a) drawing a plurality of polymeric filaments comprising a naphthalene dicarboxylate derivative;

ba) providing a fabric having an inner and outer surface and first and second ends, said fabric having a plurality of said drawn polymeric filaments ~~comprising a naphthalene dicarboxylate derivative~~, said fabric being stable at a temperature of at least about 120°C;

cb) selecting a textile construction

de) forming said prosthesis in accordance with a textile pattern; and

ed) steam sterilizing said prosthesis.

19. (New) The implantable prosthesis according to claim 1, wherein said drawn polymeric yarns further increase tenacity of said prosthesis.

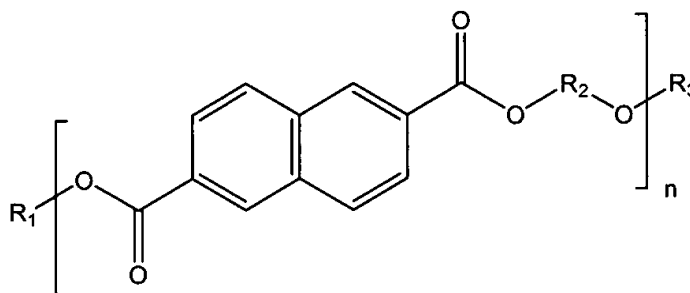
20. (New) The implantable prosthesis according to claim 18, wherein the step of drawing a plurality of polymeric filaments further comprises drawing said polymeric filaments to a point just prior to the fracture point.

21. (New) An implantable prosthesis having improved mechanical and chemical properties comprising:

a radiation resistant and hydrolytically stable biocompatible fabric having inner and outer surfaces and first and second ends;

said fabric having a textile construction of a plurality of polymeric filaments comprising a naphthalene dicarboxylate derivative, wherein said radiation resistant and hydrolytically stable biocompatible fabric is stable at a temperature of at least about 120°C,

wherein said naphthalene dicarboxylate derivative conforms to the formula:



wherein R₁ and R₃ are the same or different groups and are independently selected from the group consisting of hydrogen radicals and methyl radicals; R₂ is an alkylene radical having 1 to 6 carbon atoms which may be linear or branched; and n is from about 10 to about 200.